



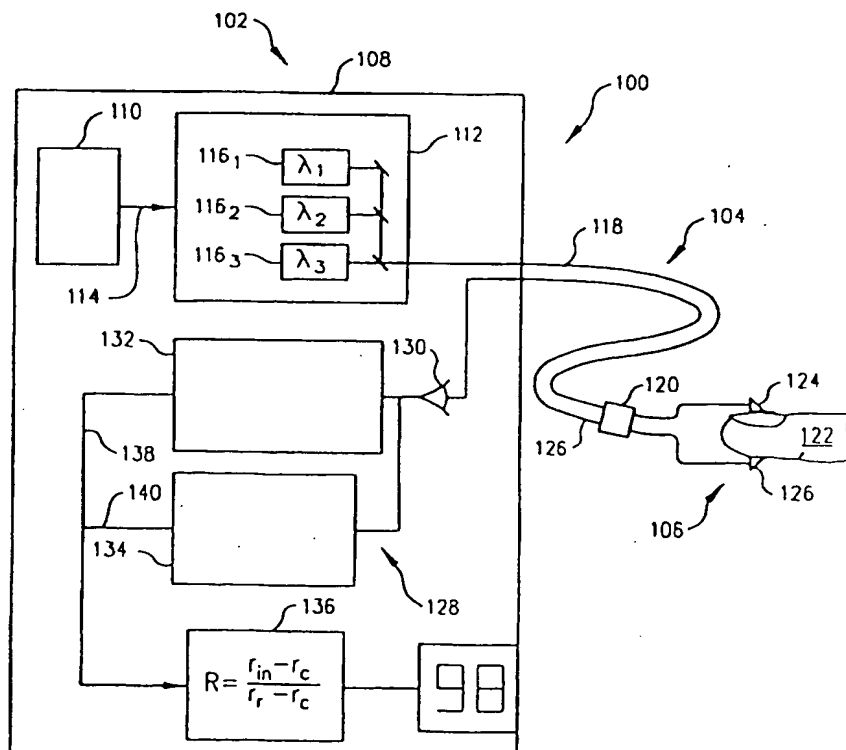
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61B 5/00		A1	(11) International Publication Number: WO 97/49330
			(43) International Publication Date: 31 December 1997 (31.12.97)
(21) International Application Number: PCT/US97/11263 (22) International Filing Date: 27 June 1997 (27.06.97) (30) Priority Data: 08/670,155 27 June 1996 (27.06.96) US (71) Applicant: FALCON MEDICAL, INC. [US/US]; 14570 N.E. 95th Street, Redmond, WA 98052 (US). (72) Inventors: SHEMWELL, David, M.; Apartment 398, 2415 42nd East, Seattle, WA 98105 (US). BROWN, Andrew, J., W.; 25619 S.E. Tiger Mountain Road, Issaquah, WA 98027 (US). NORSEN, Marc, A.; 14006 N.E. 181st Place #B205, Woodinville, WA 98072 (US). (74) Agent: STORWICK, Robert, M.; P.O. Box 386, Mercer Island, WA 98040-0386 (US).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published With international search report.	

(54) Title: MOTION ARTIFACT RESISTANT OXIMETER USING THREE WAVELENGTHS

(57) Abstract

A method and apparatus for making motion artifact-resistant pulse oximeter measurements using three wavelengths of light, and a method for its use. Light energy production circuits (112) produce pulses of at least three distinct wavelengths of light, such as through laser diodes. The pulses are cyclically transmitted through a portion of a patient's body, such as a finger (122), and signals representing the amount of light at the three distinct wavelengths are transmitted to signal processing circuits (128). The signal processing circuits produce signals indicative of the blood oxygen saturation levels of the patient's blood and of the presence of motion artifacts.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

Description

MOTION ARTIFACT RESISTANT OXIMETER USING THREE WAVELENGTHS

Technical Field

5 The present invention relates to pulse oximetry, and more particularly, to apparatus and methods for pulse oximetry
10 measurements.

Background of the Invention

In current clinical practice pulse oximeters which use a combination of two light emitting diodes (LEDs), one red and
15 one infrared, are used to monitor the patient functional blood oxygen saturation (SaO_2). In many cases the probe portion of the pulse oximeter is designed to be disposable. The design of current art reusable probe normally consists of a clamshell
20 type plastic housing for enclosing one of the patient's fingers. The LED emitters are usually situated in the part of the housing designed to cover the fingernail, and the detector (usually a photodiode) is situated in the portion of the housing designed to cover the pad of the fingertip. The
25 electrical cable which transmits the signals back to the pulse oximeter monitor usually emanates from the part of the housing on the dorsal side of the clamshell housing.

In the case of disposable probes the emitter and detector components are usually embedded in a sandwich of plastic layers which contain the wires and LED detectors which are
30 laminated to a layer of tape. In use, the disposable probe is wrapped around the fingertip and the tape is wrapped to adhere to both the finger and the outside of the probe. After application of the probe, the end of the patient's finger is nearly immobilized by the tape/probe structure. The purpose of
35 this immobilization is to reduce finger motion and thus reduce motion artifact. This system is not comfortable for the

patient and is ineffective in reducing motion artifact.

Summary of the Invention

According to one aspect, the invention is an apparatus
5 for performing blood oximetry measurements in the body of an individual. The apparatus including a transmit signal circuit, an optical signal circuit, a probe, and a signal processing circuit. The transmit signal circuit produces an electrical transmit signal. The optical signal circuit receives the
10 electrical transmit signal and produces at least first, second and third optical signals in response thereto. The at least first, second and third optical signals include optical energy at distinct optical wavelengths. The probe receives the at least first, second and third optical signals and transmits
15 the at least first, second and third optical signals through a portion of the body of the individual. The probe also receives the at least first, second and third optical signals after transmission through the portion of the body of the individual and produces at least first, second and third transmission
20 signals in response to the transmitted at least first, second and third optical signals. The signal processing circuit receives the at least first, second and third transmission signals and produces an indication of blood oximetry measurements in the body of the individual in response
25 thereto, regardless of whether the at least first, second and third optical signals are produced when the probe moves relative to the portion of the body of the individual.

In accordance with a second aspect, the invention is an apparatus for performing blood oximetry measurements in the
30 body of an individual in the presence of ambient light conditions. The apparatus includes a transmit signal circuit, an optical signal circuit, a probe, and a signal processing circuit. The transmit signal circuit produces an electrical transmit signal. The optical signal circuit receives the
35 electrical transmit signal and produces at least first, second and third optical signals in response thereto. Each of the at

least first, second and third optical signals includes optical energy at a distinct optical wavelength. The probe receives the at least first, second and third optical signals and transmits the at least first, second and third optical signals through a portion of the body of the individual. The probe also receives the at least first, second and third optical signals after transmission through the portion of the body of the individual and produces at least first, second and third transmission signals in response to the transmitted at least first, second and third optical signals. The signal processing circuit receives the at least first, second and third transmission signals and produces therefrom a system of equations representative of the relationships among the at least first, second and third transmission signals as a function of the SaO_2 , the system of equations being solvable to produce an unambiguous measurement of the SaO_2 .

According to another aspect, the invention is an apparatus for performing blood oximetry measurements in the body of an individual in the presence of ambient light conditions. The apparatus includes a transmit signal circuit, an optical signal circuit, a probe, and a signal processing circuit. The transmit signal circuit produces an electrical transmit signal. The optical signal circuit receives the electrical transmit signal and produces at least first, second and third optical signals in response thereto. Each of the at least first, second and third optical signals include optical energy at a distinct optical wavelength. The probe receives the at least first, second and third optical signals and transmits the at least first, second and third optical signals through a portion of the body of the individual. The probe also receives the at least first, second and third optical signals after transmission through the portion of the body of the individual, and produces at least one transmission signal in response to the transmitted at least first, second and third optical signals. The presence of variable ambient light conditions affects all of the transmitted at least first,

second and third optical signals equally and, hence, can easily be removed by signal processing techniques described herein. The signal processing circuit receives the at least first, second and third transmission signals and produces an indication of blood oximetry measurements in the body of the individual, regardless of whether the at least first, second and third optical signals are produced when the probe moves relative to the portion of the body of the individual.

10 Brief Description of the Drawings

Figure 1 is a graph of the absorption coefficient of blood as a function of wavelength of light.

Figure 2 is a graph of the alternating current (AC) signal as a function of time.

15 Figure 3 is a block diagram of a preferred embodiment of the invention.

Detailed Description of the Preferred Embodiment of the Invention

20 The motion artifact reduction that is accomplished through this invention is independent of the probe design and instead relies on the process of using three independent wavelengths of light specifically to remove common mode signal variation-induced motion artifact.

25 It is not unknown to use a variety of wavelengths of light in a pulse oximeter. However, in previous cases the introduction of the additional wavelength was done in order to examine blood gases other than oxygen. However, it is believed that the use of three wavelengths to provide a motion reference is unique to this invention. In the preferred embodiment, the three sources of the wavelengths of light are lasers, which allow the source to be located remote from the finger via a fiber optic pathway, and allow for much more precise spectral separation of the sources.

35 The present invention specifically uses three independent wavelengths, together with conventional associated

mathematical analysis, to eliminate or significantly reduce artifacts in the pulse oximetry measurement caused by common mode variations in the detected intensity of the investigating wavelengths. This common mode variation is the major component of motion artifacts in current art pulse oximetry. In principle, the measurement of this invention may be made with virtually any three wavelengths, but superior performance and enhanced practicality encourages certain wavelength choices.

Figure 1 is a graph of the absorption coefficient of blood as a function of wavelength of light, and shows a typical set of three laser wavelengths superimposed over the respective absorption curves 10 and 20 for oxygenated and deoxygenated hemoglobin. Three laser diode wavelengths (635 nm, 670 nm, 780 nm) are indicated in Figure 1. These three wavelengths are flashed on for short periods of time in cyclic sequence in a manner similar to that of a current production pulse oximeter.

It is particularly advantageous if two of the wavelengths 21, 22 are in the red portion of the spectrum and the third wavelength 23 is in the infrared portion of the spectrum. In addition it is more practical for a production pulse oximeter system for the three wavelengths chosen to correspond to red and infrared wavelengths that are available from production laser diode sources.

A typical pulse format would turn on the source of wavelength 21 from 100 to 200 microseconds, wait a similar amount of time, then turn on the source of wavelength 22 similarly, then repeat the entire sequence for wavelength 23. When recorded over time it can be seen that the absorption of each wavelength is modulated by the pressure waves of the heartbeat.

The three wavelengths 21, 22, and 23 shown are common, but other wavelengths could be used as will be understood by those skilled in the art (indeed virtually any set of three independent wavelengths can be used, although some wavelengths are more optimal than others). The three independent lasers

(or light emitting diodes, LEDs) are then strobed in the standard fashion known in the present art, and the light which has transmitted through the patient's finger is received by a detector which may be an optical fiber or a photodiode.

5 A typical absorption curve showing the AC component of absorption schematically is shown in Figure 2. Figure 2 is a graph of the alternating current (AC) signal as a function of time. If the detector is moved rhythmically with a repetition rate similar to a human pulse rate it is very easy to provoke
10 an erroneous reading in a present-day production pulse oximeter. This is the case because the movement due to the pressure pulse causes a rhythmic variation in the signal intensity, such as that shown in Figure 2.

Typical curves showing the heartbeat caused variations
15 and the common mode motion variations are shown schematically in Figure 2. When the motion-caused variations are rhythmic in nature, the pulse oximeter monitor can misinterpret them as heartbeat variations and produce the wrong answer. Sophisticated monitors can be controlled by software that
20 allows the monitor to infer the existence of motion and thus ignore the bad data. However, no current monitor is immune to common mode rhythmic motions of the detector and emitter complex.

This rhythmic signal variation is the same for all
25 wavelengths in use. Unfortunately an equal variation of signals in a current production pulse oximeter also corresponds to a blood oxygen saturation of about 85%, therefore current production pulse oximeters have a hard time discriminating between motion and an 85% blood oxygen
30 saturation condition of a patient. With three wavelengths there is never a physiologically viable condition where all three measurements will vary equally, due to blood oxygen saturation levels. This is the fundamental basis of this invention.

35 Figure 3 is a block diagram of a preferred embodiment of the invention. When assessed as functions of time, the three

light signals each show a time-varying amplitude modulation which is caused when the pressure waves of the heartbeat produce an expansion of the body at the measurement site. In addition, there may be amplitude variations caused by motions of the receiver and detectors.

The block diagram in Figure 3 shows the process by which three wavelengths are used to eliminate common mode motion artifact. In general, the data is gathered by the standard pulse oximetry technique, and then subjected to mathematical analysis to solve for the three unknowns (oxygenated-deoxygenated blood, scattering and absorption of all other sources, and common mode signal variations), in the presence of the three measured quantities.

In one embodiment, the signals representing the data are processed to represent normalized values and then the resulting signals are ratioed in order to form a single index which determines SaO_2 in the presence of common mode signal variations which affect the measurements at all three wavelengths, such as motion artifact.

Those skilled in the relevant mathematical arts will recognize the techniques of using measurements due to the three different wavelengths of light as methods of inverting the measurement system's equation matrix. There are many specific methods which will allow such a solution. Even in the case where the equations are not linear, they can be solved by, for example, developing a linear approximation or by the use of calibration tables. Those skilled in the arts will recognize that all such methods are equivalent or close approximations to the first method (using ratios of measurements) via the Uniqueness Theorem of Linear Systems. Therefore all equivalent mathematical techniques should be considered within the purview of this invention. The normalized ratio, once calculated, is related to the patient's blood oxygen saturation through a calibration curve and is displayed on a conventional monitor.

In addition to the foregoing method, it is possible,

using the three wavelengths, to make two independent two wavelength measurements of SaO_2 . Motion would be revealed as a discrepancy between the two measurements. This additional method can be used to check the results from the first method and to reduce random or systematic non-common mode noise in the final determined value of SaO_2 , which may be displayed on a monitor. These additional measurements are optional.

Figure 3 shows a functional block diagram of the current invention. The overall apparatus 100 includes signal production and analysis circuitry 102, signal conduits 104 and a pulse oximetry probe 106. The signal production and analysis circuitry 102 can be included in a single enclosure 108 (as shown) or may be distributed as necessary and as will be appreciated by those skilled in the electronic circuitry arts. The signal conduits 104 carry signals between the signal production and analysis circuitry 102 and the pulse oximetry probe 106. The signal conduits 104 can carry electrical signals (in which case they will be electrical conductors, such as stranded copper wires) or they can carry optical signals (in which case they will be optical conductors, such as optical fibers).

In the event that the signal conduits 104 are optical conductors, the signal production and analysis circuitry 102 can include a transmit signal circuit 110 that produces an electrical transmit signal. The electrical transmit signal is received by an optical signal circuit 112 over a line 114. The optical signal circuit 112 produces optical signals at three different wavelengths in response to the electrical transmit signal. Each of the three different wavelengths is produced by a separate source 116₁, 116₂, and 116₃. And then directed onto a first conduit 118 (which may be an optical fiber bundle) that carries the optical signals at the three different wavelengths to the pulse oximetry probe 106.

The three wavelength sources 116₁, 116₂, and 116₃ are shown as laser diodes which, in the preferred embodiment, are located in the enclosure 108. It is also possible that the

three separate wavelength sources could be located at the site of the pulse oximetry probe 106, where they would respond to electrical signals carried by the first conduit 118 to the pulse oximetry probe 106. In either case, the three wavelength sources 116₁, 116₂, and 116₃ could be LEDs rather than laser diodes. If desired, the signal conduits 104 can be detachable from the pulse oximetry probe 106 at a connector 120. This enables the pulse oximetry probe 106 to be discarded or reprocessed for reuse, if desired. The detachable portion of the pulse oximetry probe 106 is usually connected to the patient's finger 122.

The three wavelength sources 116₁, 116₂, and 116₃ are pulsed sequentially by the transmit signal circuit 110, and the three wavelengths of light from the three wavelength sources transit the tip of the finger 122, after leaving an emitter 124. This light is received at a detector site 124, which may be either a fiber optic or a photodetector such as a photodiode. Signals, either optical or electronic, from the detector site 124 are transmitted through a return conduit 126 to the enclosure 108 for processing by a signal processing circuit 128.

The signal processing circuit 128 performs the mathematical equivalent of inverting the matrix of three equations in three signals to produce a common mode error-free pulse oximetry reading. As discussed above, one such mathematical method is via production of the super-ratio of signals. The signals received through the return conduit 126 are amplified by an amplifier 130 and then portions of the signals are sent to first and second ratio circuits 132 and 134. The first ratio circuit 132 produces the ratio of the magnitude of the first red wavelength signal to the magnitude of the infrared wavelength signal. The second ratio circuit 134 produces the ratio of the magnitude of the second red wavelength signal to the magnitude of the infrared wavelength signal. Signals representing these two ratios are then conducted to a final signal processing circuit 136 over

respective signal lines 138 and 140. The final signal processing circuit 136 uses the signals carrying the two ratios and dedicated electronic circuitry (including a properly programmed microprocessor and calibration tables, as
5 desired) to produce signals that indicate the current value of SaO_2 or the presence of a common mode artifact on the conventional display 138.

Other equivalent methods of mathematical reduction in the final signal processing circuit 136 will be known to those
10 skilled in the relevant arts. For example, the super-ratio measurement method can be used as a noise reduction technique, or as a check on the accuracy of the direct three wavelength measurement. The display 138 may choose the most optimal value, via additional processing in the final signal
15 processing circuit 136 under any given circumstance.

While the foregoing is a detailed description of the preferred embodiment of the invention, there are many alternative embodiments of the invention that would occur to those skilled in the art and which are within the scope of the
20 present invention. Accordingly, the present invention is to be determined by the following claims.

Claims

1. An apparatus for performing blood oximetry measurements
5 in the body of an individual, the apparatus comprising:
a transmit signal circuit to produce an electrical
transmit signal;
an optical signal circuit to receive the electrical
transmit signal and to produce at least first, second and
10 third optical signals in response thereto, the at least first,
second and third optical signals including optical energy at
at least three distinct optical wavelengths;
a probe receiving the at least first, second and third
optical signals, transmitting the at least first, second and
15 third optical signals through a portion of the body of the
individual, receiving the at least first, second and third
optical signals after transmission through the portion of the
body of the individual, and producing at least first, second
and third transmission signals in response to the transmitted
20 at least first, second and third optical signals; and
a signal processing circuit to receive the at least
first, second and third transmission signals and to produce an
indication of blood oximetry measurements in the body of the
individual in response thereto, regardless of whether the at
25 least first, second and third optical signals are modified
when the probe moves relative to the portion of the body of
the individual.
2. The apparatus of claim 1 wherein the optical signal
30 circuit comprises diode lasers for producing the at least
first, second and third optical signals.
3. The apparatus of claim 1 wherein the at least first,
second and third optical signals include an infrared signal, a
35 first red signal and a second red signal.

4. The apparatus of claim 3, wherein the signal processing circuit makes a first measurement of SaO_2 by processing the infrared signal and the first red signal, and makes a second measurement of SaO_2 by processing the infrared signal and the second red signal, the apparatus further comprising a motion artifact detection circuit to receive the first and second measurements of SaO_2 and to compare the first and second measurements of SaO_2 to detect a motion artifact, the apparatus further including a detection signal circuit to produce a detection signal if a motion artifact is detected.

5. The apparatus of claim 1, wherein the signal processing circuit makes a first measurement of SaO_2 by processing the first and second optical signals, and makes a second measurement of SaO_2 by processing the second and third optical signals, the apparatus further comprising a motion artifact detection circuit to receive the first and second measurements of SaO_2 and to compare the first and second measurements of SaO_2 to detect a motion artifact, the apparatus further including a detection signal circuit to produce a detection signal if a motion artifact is detected.

6. The apparatus of claim 1, wherein the signal processing circuit produces an indication of blood oximetry measurements in the body of the individual by processing the at least first, second and third optical signals substantially concurrently.

7. An apparatus for performing blood oximetry measurements in the body of an individual in the presence of ambient light conditions, the apparatus comprising:

a transmit signal circuit to produce an electrical transmit signal;

an optical signal circuit to receive the electrical transmit signal and to produce at least first, second and third optical signals in response thereto, each of the at

least first, second and third optical signals including optical energy at a distinct optical wavelength;

5 a probe receiving the at least first, second and third optical signals, transmitting the at least first, second and third optical signals through a portion of the body of the individual, receiving the at least first, second and third optical signals after transmission through the portion of the body of the individual, and producing at least one transmission signal in response to the transmitted at least
10 first, second and third optical signals, the at least one transmission signal being unaffected by the presence of the ambient light conditions; and

a signal processing circuit to receive the at least first, second and third transmission signals and to produce an
15 indication of blood oximetry measurements in the body of the individual, regardless of whether the at least first, second and third optical signals are modified when the probe moves relative to the portion of the body of the individual.

20 8. An apparatus for performing blood oximetry measurements in the body of an individual in the presence of ambient light conditions, the apparatus comprising:

a transmit signal circuit to produce an electrical transmit signal;

25 an optical signal circuit to receive the electrical transmit signal and to produce at least first, second and third optical signals in response thereto, each of the at least first, second and third optical signals including optical energy at a distinct optical wavelength;

30 a probe receiving the at least first, second and third optical signals, transmitting the at least first, second and third optical signals through a portion of the body of the individual, receiving the at least first, second and third optical signals after transmission through the portion of the
35 body of the individual, and producing at least first, second and third transmission signals in response to the transmitted

at least first, second and third optical signals; and

a signal processing circuit to receive the at least first, second and third transmission signals and to produce therefrom a system of equations representative of the relationships among the at least first, second and third transmission signals as a function of the SaO_2 , the system of equations being solvable to produce an unambiguous measurement of the SaO_2 .

10 9. An apparatus for performing blood oximetry measurements in the body of an individual, the apparatus comprising:

transmit signal circuit means for producing an electrical transmit signal;

15 optical signal circuit means for receiving the electrical transmit signal and producing at least first, second and third optical signals in response thereto, the at least first, second and third optical signals including optical energy at at least three distinct optical wavelengths;

20 probe means for receiving the at least first, second and third optical signals, for transmitting the at least first, second and third optical signals through a portion of the body of the individual, for receiving the at least first, second and third optical signals after transmission through the portion of the body of the individual, and for producing at
25 least first, second and third transmission signals in response to the transmitted at least first, second and third optical signals; and

30 signal processing circuit means for receiving the at least first, second and third transmission signals and for producing an indication of blood oximetry measurements in the body of the individual in response thereto, regardless of whether the at least first, second and third optical signals are modified when the probe moves relative to the portion of the body of the individual.

35

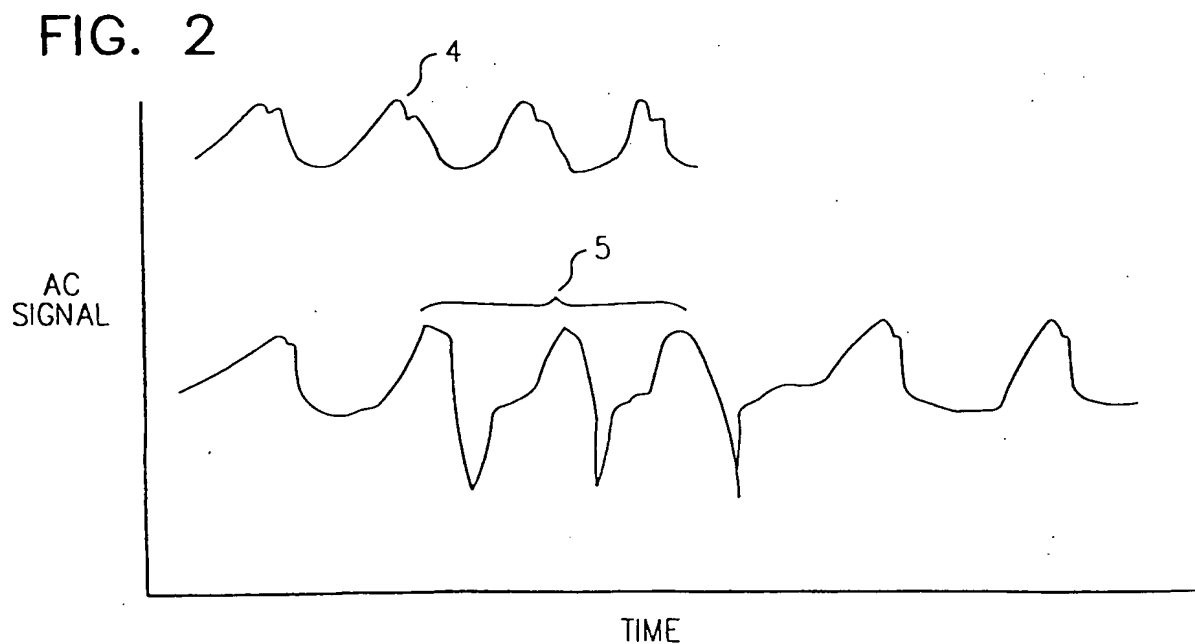
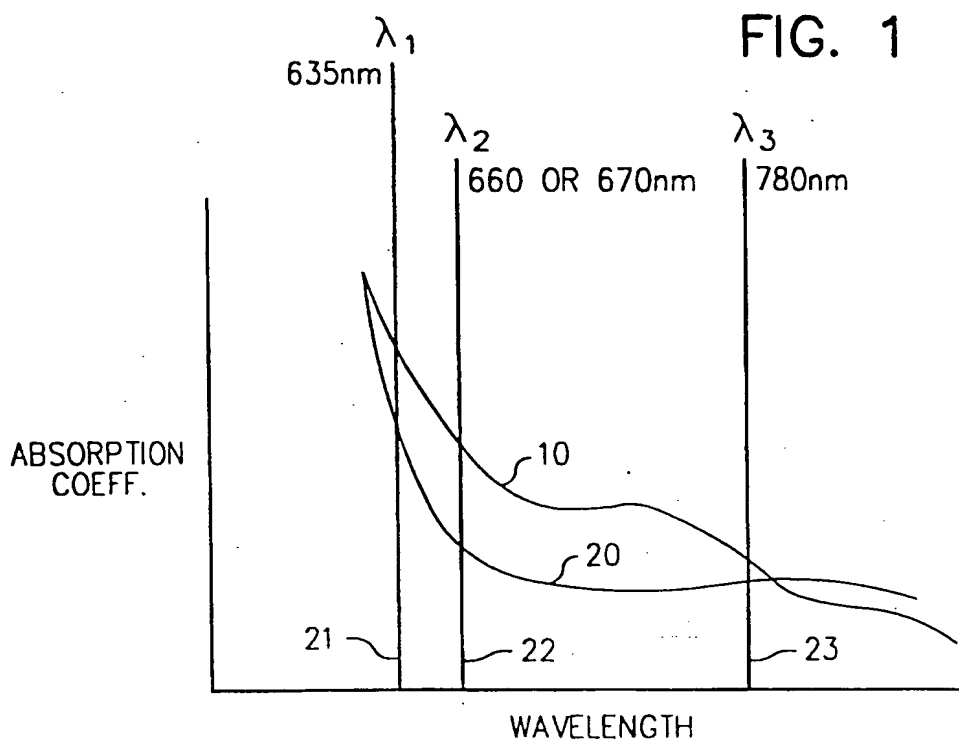
10. A method for performing blood oximetry measurements in

the body of an individual, the method comprising the steps of:

- a) producing an electrical transmit signal;
- b) receiving the electrical transmit signal;
- c) producing at least first, second and third optical
5 signals in response to the electrical transmit signal, the at
least first, second and third optical signals including
optical energy at distinct optical wavelengths;
- d) transmitting the at least first, second and third
optical signals through a portion of the body of the
10 individual;
- e) receiving the at least first, second and third optical
signals after transmission through the portion of the body of
the individual;
- f) producing at least first, second and third
15 transmission signals in response to the transmitted at least
first, second and third optical signals;
- g) receiving the at least first, second and third
transmission signals; and
- h) producing an indication of blood oximetry measurements
20 in the body of the individual in response to the at least
first, second and third transmission signals; regardless of
whether the at least first, second and third optical signals
are modified when the probe moves relative to the portion of
the body of the individual.

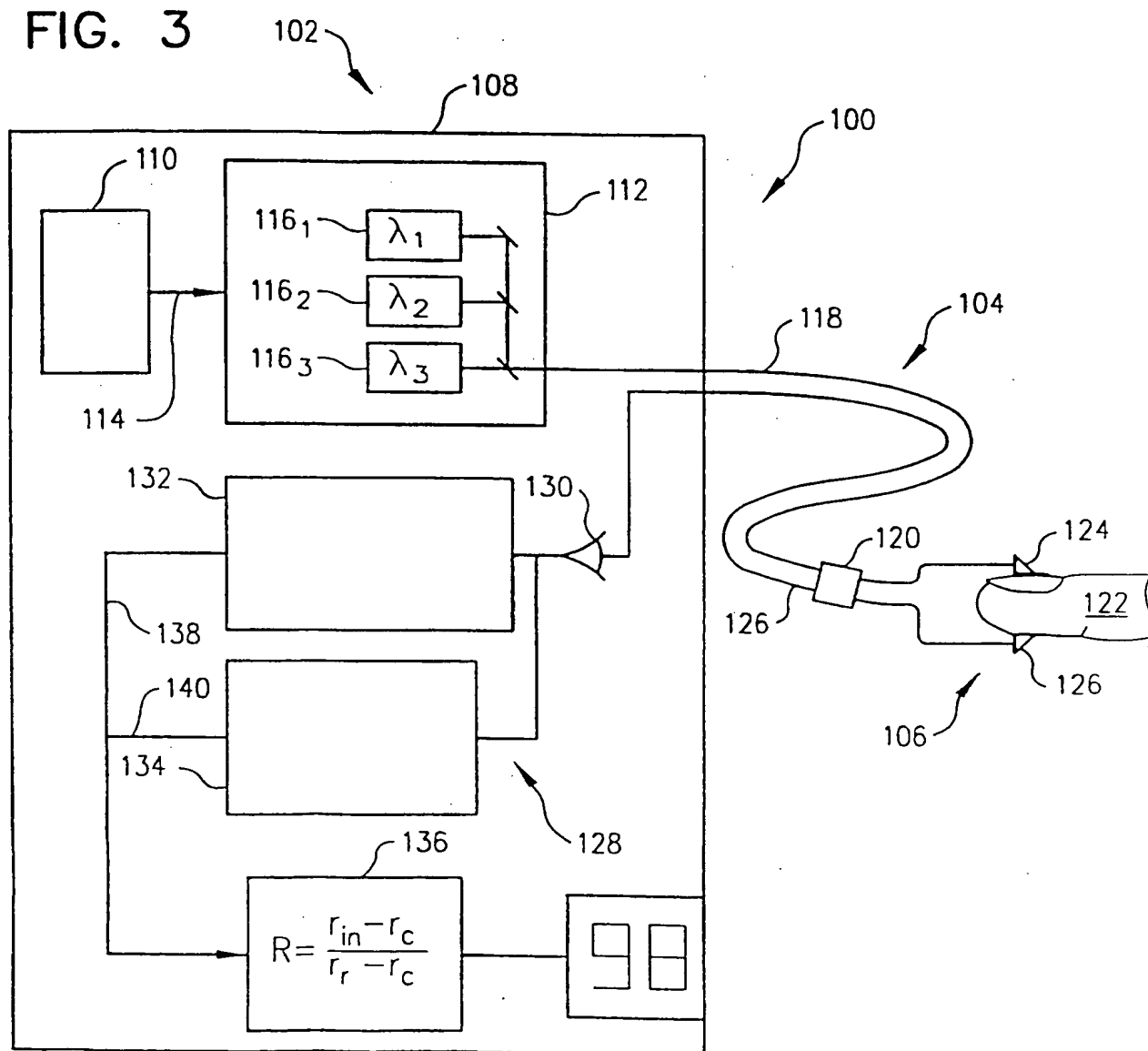
25

1/2



2/2

FIG. 3



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/11263

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61B 5/00

US CL : 128/633

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/633, 664, 665, 666: 356/41

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,714,341 A (HAMAGURI et al) 22 December 1987, column 16, line 51 - column 18, line 43.	1, 3-7, 9, and 10
X, E	US 5,645,060 A (YORKEY) 08 July 1997, column 5, line 61 - column 7, line 58.	1, 2, 3, and 6-10



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:	*T	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	*X*	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
E earlier document published on or after the international filing date	*Y*	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Z*	document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means		
P document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

07 AUGUST 1997

Date of mailing of the international search report

29 AUG 1997

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

ERIC F. WINAKUR

Telephone No. (703) 308-0858